
POLICY DETERMINATION



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 8/13/21**
(See policy history boxes for previous effective dates)

Title: Tick-Borne Encephalitis Vaccine – Ticovac™

Brief Description of Service:

Tick-borne encephalitis (TBE) is a significant cause of viral infections of the human central nervous system which is transmitted by the *Ixodes* tick species and is a flavivirus. TBE can result in permanent and severe neurological sequelae, coma, and even death in both children and adults. Preventive measures (i.e. control of tick populations, protection against tick bites [protective clothing, repellents] or vaccination against TBE) are especially important in endemic regions. TBE is the most common tick-borne central nervous system infection in Europe and Asia. It is caused by 3 subtypes of TBE virus: European, Siberian and Far-Eastern. The disease is known to have a relatively severe clinical course. There is currently no known cure or specific treatment for TBE, only maintenance therapy. Due to a considerable proportion of patients who experience long-term residual symptoms after acute illness and the increasing incidence, TBE represents a growing public health problem that could be substantially reduced with vaccination.

Although some differences are evident in several clinical and laboratory features, the course of illness is similar in children and adults. The disease severity increases with age. In general, TBE tends to present a milder illness in the pediatric population versus the adult population. However, pediatric TBE carries a high risk for residual symptoms (e.g., headache, fatigue, memory problems, irritability, concentration problems), and it can be associated with ongoing or progressive neurodevelopmental and cognitive difficulties. Approximately 70% of children display residual symptoms following the acute phase of TBE. Long term effects of a somatic nature in childhood TBE, such as severe neurologic residual (i.e., hemiparesis and epilepsy), have been reported less frequently than in adults (2% and 10%, respectively). Nevertheless, neurologic residual constitutes a significant handicap, interfering with quality of life for many years. Infected individuals older than approximately 40 years of age increasingly develop the encephalitic form of the disease. Older patients, especially those older than 60 years of age have higher risk of paralysis and death due to TBE. Paralysis occurs in 30% of patients who enter the acute phase of the illness.

World Health Organization (WHO; 2022) indicates that approximately 10,000-12,000 clinical cases of tick-borne encephalitis are reported every year with the majority of cases reported during the warm months (April-November). This figure is believed to be significantly lower than the actual number of clinical cases as not all areas are required to report illnesses and not all individuals seek treatment.

The WHO (2020) recommends vaccination to people of all age groups, including children, in highly endemic areas (≥ 5 cases/100,000 per year). In regions where the pre-vaccination incidence of TBE is low to moderate (5 year incidence < 5 cases/100,000 per year) immunization should target persons in the most vulnerable groups. The WHO also recommends TBE vaccination for people travelling from nonendemic areas to rural endemic areas up to altitudes of 1400 m.

In 2020, Pfizer submitted a biologics license application (BLA) to obtain licensure of an inactivated, whole virus, tick-borne encephalitis vaccine (Ticovac). The proposed indication is for active immunization to prevent tick-borne encephalitis in individuals 1 year of age and older. On August 13, 2021, the U.S. Food & Drug Administration approved the BLA for tick-borne encephalitis vaccine.

Ticovac includes a 3-dose regimen. The dose for individuals 1 to < 16 years of age is 0.25 mL and that for individuals 16 years and older is 0.5 mL. In individuals 1 through < 16 years of age, the second dose should be administered 1 to 3 months following the first dose. In individuals 16 years of age and older, the second dose should be administered 14 days to 3 months following the first dose. The third dose should be administered 5-12 months after the second.

In February 2022, the U.S. Advisory Committee on Immunization Practices approved recommendations for use of vaccine among persons who travel abroad and for laboratory workers in the United States.

The Centers for Disease Control (CDC; 2021) indicated the risk for TBE is very low for most travelers visiting countries where TBE is found. Travelers are at higher risk if they plan to visit areas with TBE when ticks are most active (April through November) and take part in outdoor activities in or near forested areas (i.e., hiking, camping, hunting, fishing, or birdwatching). A recommendation is made to take steps to avoid tick bites when traveling during warmer months to areas known to be endemic for tick-borne encephalitis. The CDC also recommends talking to your health care provider about vaccination if you will be participating in outdoor activities while visiting parts of Europe and Asia where TBE is endemic.

Recommendation:

TicovacTM is a vaccine indicated for active immunization to prevent tick-borne encephalitis. Ticovac is FDA approved for use in individuals 1 year of age and older.

Effective August 13, 2021 (FDA approval)

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:

90626 90627

Other codes (investigational, not medically necessary, etc.):

N/A

References:

1. Bogovic, P., Strle, F. "Tick-borne encephalitis: A review of epidemiology, clinical characteristics, and management." *World J Clin Cases* 2015 May 16; 3(5): 430-441
2. Centers for Disease Control. "Tick-borne encephalitis – Vaccine." 2022. <https://www.cdc.gov/tick-borne-encephalitis/vaccine/index.html>. Accessed September 1, 2022.
3. Centers for Disease Control. "Tick-borne encephalitis – Vaccine for Health Care Providers." 2022. <https://www.cdc.gov/tick-borne-encephalitis/healthcare-providers/hcp-vaccine.html>. Accessed September 1, 2022.
4. Fischer, M., Gould, CV., Rollin, PE. "Tickborne Encephalitis. Centers for Disease Control and Prevention. CDC Yellow Book 2020: Health Information for International Travel." New York: Oxford University Press; 2019:4(78). <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/tickborne-encephalitis>. Accessed September 1, 2022.
5. U.S. Food & Drug Administration. "BLA Approval – Tick-Borne Encephalitis." 8/13/21. <https://www.fda.gov/media/151516/download>. Accessed September 1, 2022.
6. U.S. Food & Drug Administration. Summary Basis for Regulatory Action: Ticovac, Pfizer Ireland Pharmaceuticals. <https://www.fda.gov/media/151994/download>. Accessed September 1, 2022.
7. Vaccines against tick-borne encephalitis: WHO position paper. *Wkly Epidemiol Rec* 2011; 86: 241-256. PMID: 21661276
8. World Health Organization. "Overview: Tick-borne encephalitis." 2022. https://www.who.int/health-topics/tick-borne-encephalitis#tab=tab_1. Accessed September 1, 2022.

Joint Blue Cross/BCN Medical Policy History

Policy Effective Date	Blue Cross Signature Date	BCN Signature Date	Comments
8/13/21	10/18/22		Joint policy established

Next Review Date: Policy Retired; No longer subject to annual review.